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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,474	03/05/2001	Kazuo Nagai	084335/0131	1349

22428 7590 10/21/2003

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EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 10/21/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,474

Applicant(s)

NAGAI ET AL.

Examiner

Gabriele E. BUGAISKY

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-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2003 and 18 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 10-12, 14-41 and 44-49 is/are pending in the application.
- 4a) Of the above claim(s) 10-12, 14-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 20-25, 28-29, 32-33, 36-37, 40, 41, 44-49 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 26, 27, 30, 31, 38 and 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The amendments of May and July 2003 are acknowledged. Claims 42-43 have been cancelled and new claims 44-49 have been submitted. Claims currently under consideration are 1-4, 20-41 and 44-49.

Specification

The amended title is acceptable.

Claim Objections

Claims 1-4, 22-23 are objected to because of the following informalities: The format of the claims appears to be a direct translation, and as the claims have been amended, has caused them to become unwieldy. Specifically, in claim 1, e.g., “and confers an ability to grow in.... lysozyme to a microorganism belonging to *Corynebacterium glutamicum*” (and similarly in claims 2-4) has become difficult to understand. The following is suggested and would NOT be considered new matter: “and confers to a *Corynebacterium glutamicum* microorganism an ability to grow in.. .”

Claim 1 also lacks a period.

In claim 22, “*Corynebacterium glutamicum*” is not italicized. The Examiner presumes Applicant wishes this claim to be consistent with all other claims.

In claims 22-23, line 2 “stain” presumably should be “strain”.

Appropriate correction is required.

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Claims 25-27, 29-31 and 37-39 are objected to as they depend from objected base claims 2-4.

Claims 40-41 and 44-45 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, in the interests of compact prosecution, the claims have been treated on the merits to the best extent possible..

The previous objection to claims 20, 26 and 30 is withdrawn.

Claim Rejections - 35 USC § 101

The rejection of claims 1-3 , 20-22 , 24-26 and 28-30 under 35 U.S.C. 101 for non-statutory subject matter is withdrawn, based upon the amendment.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejection of claims 4, 23, 27, 31, 35 and 39 under 35 U.S.C. 112, first paragraph, is withdrawn, as assurance of public availability has been made.

Claims 1, 2 20-21, 24-25, 28-29, 32-33, 36-37 40-41 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for DNA encoding

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the protein of SEQ ID NO:2, which upon expression confers lysozyme insensitivity to strains that are lysozyme sensitive, constructs containing this DNA and a method of making the protein of SEQ ID NO:2 does not reasonably provide enablement for any DNA which encodes a mutated protein derived from SEQ ID NO:2, or a DNA which encodes a protein which has a certain degree of sequence similarity to SEQ ID NO:2 that upon expression confers lysozyme insensitivity to strains that are lysozyme sensitive. Similarly, constructs containing such DNA and methods of making proteins using these constructs are also not enabled.

The discussion of the previous action is incorporated here Applicant's arguments filed 5/20/2003 have been fully considered but they are not persuasive. Applicant discussed a DNA that hybridizes under stringent conditions and that is 60% or more homologous and confers lysozyme sensitivity. First, please note that the Examiner has withdrawn the rejection of claims reciting the hybridization conditions. With respect to the claimed sequence identity of the encoded protein, the deletion mutant is a specific example of a fragment which encodes a protein with 60% identity to SEQ ID NO:2. The fragment has sequence identical to SEQ ID NO:2 in the region of overlap and indicates that other portions of the protein are not essential to its functional ability for lysozyme sensitivity. The claims, however, encompass nucleotides encoding any protein with 60% identity to SEQ ID NO:2, with an unknown number of substitutions, deletions and insertions; and the only working example is a nucleotide encoding a fragment of SEQ ID NO:2.

The previous rejection of claims 3, 22, 26, 30, 34 and 42 under 35 U.S.C. 112, first paragraph, for scope of enablement is withdrawn, based upon the amendment.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-23 , 40-41, 44-45 and 46-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear in claims 20-23 that the lysozyme sensitivity of the strain is prior to transformation. It is suggested that the following. e.g., be incorporated in each claim after "lysozyme" "prior to transformation with said DNA".

Claims 40-41 and 44-45 are included in this rejection as they read upon the above claims and do not clarify the ambiguity.

It is not clear in claim 46 what is intended by a nucleotide corresponding to nt 271=1593 of SEQ ID NO:1. Does the nucleotide bear some undefined degree of identity or does it comprise the recited nucleotides of SEQ ID NO:1?

Claims 47-49 are included in this rejection as they read upon the above claim and do not clarify the ambiguity.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 10-12 and 14-19 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

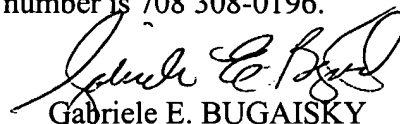
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.



Gabriele E. BUGAISKY
Primary Examiner
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October 20, 2003